February 2007

Virginia Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

6603 W Broad St, 5th Floor
Richmond, VA 23230-1712
Phone: 804/662-9911
www.dhp.virginia.gov/pharmacy

Scope of Practice

Some pharmacists appear to be confused when trying to determine the validity of a prescription related to scope of practice. The Virginia Board of Pharmacy frequently receives calls from pharmacists who are concerned, for example, with an ophthalmologist writing a prescription for an oral contraceptive, or a gynecologist prescribing for a male, or a pediatrician prescribing for an adult. Some of the confusion may come from language in laws that describe what constitutes a valid prescription. The following sentences and phrases are some of the culprits causing the confusion that a prescriber may not prescribe outside the scope of his or her specialization:

- "shall be issued for **a medicinal or therapeutic purpose** and may be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship"
- "shall only prescribe, dispense, or administer controlled substances [CS] in good faith for medicinal or therapeutic purposes **within the course of his [or her] professional practice**"
- "**in good faith** to his [or her] patient for a medicinal or therapeutic purpose **within the course of his [or her] professional practice**"
- "No prescription shall be filled unless there is a bona fide practitioner-patient-pharmacist relationship. A prescription not issued in the **usual course of treatment** or for authorized research is not a valid prescription."

Essentially, practitioners of medicine or osteopathic medicine have the broadest scope of practice. Practitioners of medicine and osteopathic medicine complete a program at a school of medicine or osteopathic medicine. The practice of medicine involves the prevention, diagnosis, and treatment of human physical or mental ailments, conditions, diseases, pain, or infirmities, and therefore, a practitioner of medicine receives basic training in a large number of disease states that affect patients of all ages. The Virginia Board of Medicine issues all practitioners of medicine the same type of license. It does not license practitioners of medicine by their specialized field of expertise. Thus, obstetricians/gynecologists, ophthalmologists, psychiatrists, neurologists, etc, are all licensed by the Board of Medicine with the same license, which legally authorizes them to perform medicine and surgery in the broadest sense. Additionally, the Drug Control Act does not limit the schedules of drug that a practitioner of medicine may prescribe. Therefore, if a prescriber is a practitioner of medicine regardless of his or her specialty and is comfortable treating a patient's condition, then he or she may legally prescribe any drug within Schedules II-VI for this condition. For example, if a psychiatrist wishes to treat a patient's migraine headaches, then he or she is within his or her right to prescribe drugs, including Schedule II drugs, for this condition. Additionally, if an obstetrician/gynecologist chooses to manage a patient's hypertension then he or she may exercise his or her right to prescribe a drug within any schedule for that purpose. This same interpretation of the scope of practice is true for practitioners of osteopathic medicine, as well.

Prescribers who are not practitioners of medicine or osteopathic medicine such as dentists, podiatrists, therapeutic pharmaceutical agent (TPA)-certified optometrists and veterinarians have a more limited scope of practice because their professional licenses authorize the treatment of specific areas of the body or specific population groups. Therefore, these prescribers may not prescribe drugs that are intended to treat conditions for which their licenses do not authorize. For example, a dentist may probably not prescribe an albuterol inhaler since the drug is not typically used for the treatment of the oral cavity or the maxillofacial, adjacent and associated structures. Similarly, veterinarians may not prescribe drugs for human consumption because their licenses are restricted to treatment of animals.

The prescribing authorities of nurse practitioners and physician assistants are limited, dependent prescriptive authorities, and therefore, the scope of practice is determined by the scope of practice of the supervising practitioner and what is authorized in the practice agreement. For a summary of the prescriptive authority for all prescribers, please refer to guidance document 110-8 at *www.dhp.virginia.gov/pharmacy/guidelines/110-08.doc.*

Pharmacists should continue the consideration of all factors in determining the validity of a prescription, to include the presence of a bona fide prescriber-patient relationship as defined in §54.1-3303 of the Code of Virginia, whether the prescribing was done in good faith, which can be somewhat subjective, and whether the prescription was written for a medicinal or therapeutic purpose. The "usual course of treatment" usually refers to approved indications or other scientifically accepted indications for a drug. "Within the course of his professional practice" is not intended to necessarily limit prescribing to a particular specialization.

Required Information for Written Prescriptions

As stated in §54.1-3408.01 of the Drug Control Act, a written prescription must capture certain information to be valid. It must be written with ink or individually typed or printed; prepared by

Continued on page 4

National Pharmacy C

(Applicability of the contents of articles in the National Pharmacy Compli
and can only be ascertained by examining

FDA Issues Nationwide Alert on Counterfeit One-Touch Blood Glucose Test Strips

In mid October 2006, United States Food and Drug Administration (FDA) alerted the public to counterfeit blood glucose test strips being sold in the US for use with various models of LifeScan, Inc, One Touch Brand Blood Glucose Monitors. The counterfeit test strips potentially could give incorrect blood glucose values; either too high or too low. At press time, no injuries have been reported to FDA.

Consumers who have the counterfeit test strips should be instructed to stop using them, replace them immediately, and contact their physicians. Consumers with questions may contact the company at 1-866/621-4855. The counterfeit test strips were distributed to pharmacies and stores nationwide – but primarily in Ohio, New York, Florida, Maryland, and Missouri – by Medical Plastic Devices, Inc, Quebec, Canada and Champion Sales, Inc, Brooklyn, NY.

The counterfeit test strips and their characteristics are:

- One Touch Basic®/Profile®
  - Lot Numbers 272894A, 2619932, or 2606340
  - Multiple Languages – English, Greek, and Portuguese text on the outer carton
  - Limited to 50-Count One Touch (Basic/Profile) Test Strip packages
- One Touch Ultra®
  - Lot Number 2691191
  - Multiple Languages – English and French text on the outer carton
  - Limited to 50-Count One Touch Ultra Test Strip packages

LifeScan has alerted the public via a press release and has notified pharmacists, distributors, and wholesalers through a letter. In its letter, the company advises customers to contact their original source of supply for restitution. For more information, visit *www.GenuineOneTouch.com.*

New DEA Number Assignments; Updated DEA Practitioner's Manual Released

In early November 2006, Drug Enforcement Administration announced that due to the large Type A (Practitioner) registrant population, the initial alpha letter "B" has been exhausted. The Agency, therefore, has begun using the new alpha letter "F" as the initial character for all new Type A (Practitioner) registrations. For more information, visit *www.deadiversion.usdoj.gov/drugreg/reg_apps/new_reg_number110906.htm.*

Additionally, in August 2006, the Agency released the Practitioner's Manual, An Informational Outline of the Controlled Substances Act, 2006 Edition. The Manual, prepared by the Agency's Office of Diversion Control, is designed to assist practitioners (physicians, dentists, veterinarians, and other registrants authorized to prescribe, dispense, and administer controlled substances) in their understanding of the Federal Controlled Substances Act and its implementing regulations as they pertain to the practitioner's profession. The Manual can be accessed at *www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual090506.pdf.*

Optimizing Computer Systems for Medication Safety

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Computers that are used by pharmacists are essential professional tools that can increase staff efficiency and support effective drug utilization review and therapeutic drug monitoring. At the same time, pharmacists must not place sole reliance on this tool as a means to protect patients from drug-induced harm.

Many of today's computer order-entry systems provide vendor-defined and user-defined alerts that remind or warn staff about potential drug-related problems during order entry. The Institute for Safe Medication Practices (ISMP) often recommends these alerts as a way to inform staff about potential errors. However, pharmacists have expressed concern that the sheer number of warnings that appear on the screen during order entry can be overwhelming and slow the process. In many cases, clinically insignificant warnings are as likely to appear as those that are vital. As a result, staff may inadvertently bypass critical warnings, especially when the workload is high. This is easy to do with many systems.

In an informal survey on computer systems, we found that all too often it simply requires striking the "enter" key to bypass an alert, even those that could prevent serious or fatal errors. Also, if the system forces a response to the warning, practitioners who feel pressured to rush through order entry may select the first reason listed on the screen instead of appropriately addressing the issue. Another issue is that when pharmacists are properly alerted to a potential allergic reaction or harmful drug interaction, they may erroneously assume that the prescriber is already aware of the problem and fail to alert the prescriber directly.

When practitioners become accustomed to receiving unimportant or clinically irrelevant warnings they often ignore these "false alarms," or turn them off, at least mentally. Here are some strategies that can be used to optimize the effectiveness of alerts and minimize the possibility of overlooking the more significant ones:

- Use a tiered system for interactive warnings that allows staff to view and consider possible warnings but easily bypass less serious issues, if appropriate. Require a text entry to describe the response to more significant alerts.

- Pharmacies should assign pharmacists who enter orders the task of noting any warnings that they feel are not clinically significant. The severity level of certain alerts may need to be changed in order not to "overload" the pharmacist. However, wholesale changing of severity levels according to vendor specifications should be done with caution. Check with your vendor to fully understand how they assign severity levels before making any changes to ensure you are not missing warnings you deem to be critical.
- Make significant alerts as visible as possible. Some systems may allow large screen fonts in a contrasting color, flashing messages, sounds, or other means of distinguishing the alert.
- Maximize a system's capabilities whenever possible by incorporating serious error-prone situations that have been reported in this column as well as other publications.
- Review non-interactive pop-up messages on an ongoing basis, such as the ones we suggest for avoiding drug name mix-ups. Delete any that are no longer applicable.
- Apply auxiliary labels to drug packages and storage shelves to warn about unclear or confusing labeling and packaging, instead of using certain messages in the computer system.
- Consider printing warnings on drug labels or medication storage areas instead of building alerts into the order entry process. For example, print "Topical or External Use Only" warnings on drug labels for all drugs that can be administered safely only by this route.
- Many systems are capable of providing reports about all warnings that have been overridden. Assign a clinician or manager to review the report daily and periodically identify those warnings that are continually overridden. Share report results with staff members before changes are made to the computer system. Consider focusing on one or two common but critically important warnings to monitor the effectiveness of the computer's alert system and the response to the alert.

Revised Coumadin Labeling and Medication Guide

FDA and Bristol-Myers Squibb notified pharmacists and physicians of revisions to the labeling for Coumadin®, to include a new patient Medication Guide as well as a reorganization and highlighting of the current safety information to better inform providers and patients.

The FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern.

Information about all currently approved Medication Guides is available at *www.fda.gov/cder/Offices/ODS/medication_guides.htm.*

To access the new Medication Guide, revised prescribing information and supplemental supporting documents, visit *www.fda.gov/medwatch/safety/2006/safety06.htm#Coumadin.*

FTC and FDA Act Against Internet Vendors of Fraudulent Diabetes Cures and Treatments

The Federal Trade Commission (FTC) and FDA, working with government agencies in Mexico and Canada, have launched a drive to stop deceptive Internet advertisements and sales of products misrepresented as cures or treatments for diabetes. The ongoing joint campaign has so far included approximately 180 warning letters and other advisories sent to online outlets in the three countries.

The joint diabetes initiative to stop commercial sale of fraudulent therapies originated with a Web surf for "hidden traps" by the International Consumer Protection and Enforcement Network, an organization of law enforcement authorities, members of the Mexico, United States, and Canada Health Fraud Working Group (MUCH), and the attorneys general offices of Alaska, Michigan, Ohio, Virginia, and Wisconsin. MUCH, which consists of regulatory officials from health, consumer, and competition protection agencies in the three North American countries, had previously conducted a campaign against fraudulent weight-loss products. Using the results of the Internet sweep, FTC sent warning letters for deceptive ads to 84 domestic and seven Canadian Web sites targeting US consumers, and referred an additional 21 sites to foreign governments. About a quarter of the firms have already changed their claims or removed their pages from the Internet, and several others are in contact with FTC.

FTC also announced a new consumer education campaign to teach consumers how to avoid phony diabetes cures. The materials encourage consumers to "Be smart, be skeptical!" and will be available in English, Spanish, and French. One component is a "teaser" Web site available at *http://wemarket4u.net/glucobate/index.html.* At first glance, the site appears to be advertising a cure for diabetes called Glucobate, but when consumers click for more information on ordering the product, it reveals information about avoiding ads for phony cure-alls in the future. The new education materials, including a bookmark and consumer alert, were introduced to coincide for Diabetes Awareness Month in November.

FDA Implements Strategy for Phony Dietary Supplement Claims

FDA has developed a strategy to focus its enforcement efforts in the area of dietary supplements. The strategy was designed to address illegal dietary supplement ingredients and ensure integrity and truthful labeling of dietary supplements. One emphasis is on claims aimed at patients with serious diseases such as cancer and diabetes. Over an approximate 12-month time frame, the Agency has sent more than 100 warning letters and other advisories to Internet firms and has seized products at one firm. In addition, the Agency maintains special Web sites, in English and Spanish, which amplify the Agency's counsel to consumers to check with their doctor, nurse or pharmacist before trying any new health care product. These materials cover a broad range of subjects of special interest to patients with diabetes (*www.fda.gov/diabetes/; www.fda.gov/diabetes/pills.html; www.fda.gov/opacom/lowlit/diabetes.html; www.fda.gov/opacom/lowlit/sdiabetes.html*), as well as more general health care information.

Continued from page 1

the prescriber or by an agent for the prescriber's signature; and shall contain the name, address, and telephone number of the prescriber. A prescription issued by a nurse practitioner must also contain his or her 10-digit prescriptive authority license number beginning with 0017. Additionally, a prescription issued by a physician assistant must bear both the name of the supervising physician and of the physician assistant. The prescriber's information shall be either preprinted upon the prescription blank, electronically printed, typewritten, rubber stamped, or printed by hand. A prescription written for a CS other than one controlled in Schedule VI shall also contain the Drug Enforcement Administration (DEA) number assigned to the prescriber. Please note that a prescription written for a Schedule VI drug does not need to legally bear the prescriber's DEA number, nor must a prescriber possess a DEA number should he or she only prescribe Schedule VI drugs.

Additional information that must be recorded on a written prescription includes: the first and last name of the patient for whom the drug is prescribed; the address of the patient, which must either be placed upon the written prescription, or if not otherwise prohibited by law, the dispenser may record the address of the patient in an electronic prescription dispensing record for that patient in lieu of recording it on the prescription; the date when issued; and the signature of the prescriber signed on the date of issue. Please remember that if the prescriber electronically generates a prescription but prints it out to be handed to the patient, then it must bear a manual signature. An electronic signature is not valid for written prescriptions but is valid for electronically transmitted prescriptions; and an electronic signature may or may not appear as an electronic image of a signature. Lastly, no written prescription order form shall include more than one prescription per form except as exempted from this requirement in 54.1-3408.01.

For more information on the requirements of written prescriptions, please refer to 54.1-3408.01 of the Drug Control Act at *www.dhp.virginia.gov/pharmacy/leg/Pharmacy%20Law%202006.doc#_Toc139952212* and guidance document 110-35 at *www.dhp.virginia.gov/pharmacy/guidelines/110-35%20Requirements%20for%20prescriptions%201-2005.doc*.

Dispensing Buprenorphine

The federal Drug Addiction Treatment Act of 2000 (DATA) has significantly changed how physicians may treat opioid addiction. Previously, physicians who wanted to maintain a patient on controlled opioid therapy for treatment of an addiction had to refer patients to specialized opioid treatment programs and were not allowed by federal law to write prescriptions for treatment of opioid addiction. However, DATA now allows qualified physicians to treat opioid addiction in office-based settings with Schedule III-V CS specifically approved by Food and Drug Administration for addiction treatment.

To date, the only drug that has been approved for office-based treatment of opioid addiction is buprenorphine, commercially available as Subutex® and Suboxone® (buprenorphine/naloxone). Please be aware that any pharmacy may order and dispense buprenorphine pursuant to a prescription, and pharmacies do not need a special DEA registration to dispense buprenorphine. There are some additional requirements for prescribers who want to provide office-based treatment by using buprenorphine.

Prior to prescribing buprenorphine to treat addiction, the qualified physician must first meet criteria for, and receive approval from, the Substance Abuse and Mental Health Services Administration (SAMHSA). Additionally, the prescriber must also apply for and receive approval from DEA. The DEA identification number issued for approval to use buprenorphine for addiction treatment will be the same number as the prescriber's regular DEA number but will begin with the letter X instead of A, B, or F. In addition to the regular DEA number, the prescriber shall also record the "X" DEA number on any prescription written for treatment of opioid addiction.

Additional information regarding the prescribing of buprenorphine may be accessed at *www.buprenorphine.samhsa.gov/*. To verify a physician's waiver to prescribe buprenorphine for the treatment of opioid addiction, please contact the Center for Substance Abuse Treatment Buprenorphine Information Center at 1-866/BUP-CSAT (1-866/287-2728) or via e-mail at info@buprenorphine.samhsa.gov.

Are You Using the Prescription Monitoring Program?

In 2005, the prescription monitoring program (PMP) processed 1,791 requests for dispensing information. In 2006, the state-wide expanded program processed 6,333 requests for information – more than three times the number of requests processed in 2005. As of December 29, 2006, there were 8,183,138 records in the PMP database and 608 registered users of the PMP Data Center. Over 330 practitioners are registered to request and receive information from the PMP Data Center while only 167 pharmacists are registered.

As a registered user of the PMP Data Center, a pharmacist may request a query of the database for a specific individual's treatment history involving Schedules II, III, and IV drugs to assist the pharmacist in ruling out the possibility that a patient is "doctor shopping" or "scamming" in order to obtain CS. All information obtained from the PMP Data Center is confidential and may not be shared with any other individual. It is intended to be a tool used solely by the person making the request when presented with a questionable prescription. If a pharmacist wishes to convey concerns to the prescriber resulting from the pharmacist having received a report from the PMP Data Center, the pharmacist should simply advise the prescriber to make a request from the PMP Data Center; however, specific drug information on the pharmacist's report may not be legally shared with the physician.

Pharmacists in receipt of reports from the PMP Data Center may not file these reports with prescription records. The reports may either be shredded or filed in a manner within the pharmacy that will maintain confidentiality of the information with access restricted to the requesting pharmacist. Also, please remember to comply with Board regulation 18VAC110-20-270 when declining to dispense any prescription. This rule requires the pharmacist to record on the back of the prescription the word "declined"; the name, address, and telephone number of the pharmacy; the date filling of the prescription was declined; and the signature of the pharmacist. Pharmacists do not have to record the reason for declining the dispensing of a prescription. If the declining resulted from a report received from the PMP Data Center and another pharmacy is questioning the reason for declining the prescription, you should simply advise them to make a request to the PMP Data Center. You may not legally share specific drug information from the report with this pharmacist.

For more information about registering for the PMP Data Center, please click on *www.dhp.virginia.gov/dhp_programs/pmp/pmp_pharmacist.asp,* and for a listing of frequently asked questions, please refer to *www.dhp.virginia.gov/dhp_programs/pmp/docs/Questions%20for%20pharmacists.doc*.

The *Virginia Board of Pharmacy News* is published by the Virginia Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Elizabeth Scott Russell, Executive Director - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Larissa Doucette - Editorial Manager